

Itraconazole Syrup 40 mg/mL

INGREDIENTS:

Itraconazole 100 mg capsule	48 capsules
Ethyl alcohol USP	8–10 mL
Simple syrup NF	QSAD: 120 mL

EQUIPMENT AND SUPPLIES:

Powder containment hood, glass mortar and pestle, graduated cylinder

PREPARATION DETAILS:

1. Open capsules and empty contents into a mortar.
2. Add alcohol to beads and let it stand for 3 to 4 minutes to soften the beads.
3. Triturate beads to a fine powder.
4. Levigate powder with a small amount of vehicle to form a paste.
5. Add vehicle in increasing amounts while mixing thoroughly.
6. Transfer contents of the mortar to a graduated cylinder.
7. Rinse the mortar and pestle with vehicle and pour into graduated cylinder.
8. Add vehicle to the graduated cylinder to achieve the total volume indicated above.
9. Transfer contents of the graduated cylinder into an appropriately sized amber bottle.
10. Shake well to mix.

Quality-Control Procedures — Visually inspect for physical appearance of formulation and container closure integrity (no leakage, cracks in container, or improper seals).

Labeling Requirements — Extemporaneously compounded preparation. For oral use only. Store in refrigerator. Shake well before use.

Storage Conditions/Stability — Refrigerate. Stable for 35 days.

STABILITY STUDY DETAILS:

Study Container Type — Amber type III glass prescription bottle with child-resistant cap

Referenced Manufacturers — Itraconazole capsules (Sporanox, Janssen Pharmaceuticals); alcohol (McCormick Distilling Co); simple syrup (Humco).

Stability-Indicating Study — Yes

Commercially available as a 10-mg/mL solution — Use extemporaneously prepared formulation only when commercial product is unavailable or a more concentrated suspension is desired. Extemporaneously prepared suspension may not achieve same bioavailability as commercially available formulation. Monitoring of serum itraconazole concentration may be warranted.

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Itraconazole Syrup 40 mg/mL (continued)

REFERENCES

1. Jacobson PA, Johnson CE, Walters JR. Stability of itraconazole in an extemporaneously compounded oral liquid. *J Health Syst Pharm.* 1995;52:189-191.
2. Villarreal JD, Erush SC. Bioavailability of itraconazole from oral liquids in question. *Am J Health Syst Pharm.* 1995;52(15):1707-1708.
3. Christensen KJ, Gubbins PO, Gurley BJ, et al. Relative bioavailability of itraconazole from an extemporaneously prepared suspension and from the marketed capsules. *Am J Health Syst Pharm.* 1998;55:261-265.